



1632  
84

**PATENT**

**ATTORNEY DOCKET NO: BAL-106 (17349)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                                       |   |                           |
|---------------------------------------|---|---------------------------|
| In re Application of Marshall, et al. | ) | Examiner: Louise N. Leary |
|                                       | ) |                           |
| Serial No: 09/977,874                 | ) | Art Unit: 1632            |
|                                       | ) |                           |
| Filed: October 15, 2001               | ) | Deposit Acct. No: 04-1403 |
|                                       | ) |                           |
| Confirmation No: 3775                 | ) | Customer No: 22827        |
|                                       | ) |                           |
| For: Composition For The Detection Of | ) |                           |
| Gastrointestinal Disorders            | ) |                           |

**TRANSMITTAL LETTER**

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Please find attached an Information Disclosure Statement for the above-captioned application and copies of the disclosed references. Also find enclosed a copy of a Notice of References Cited, dated September 8, 2003, for related application having serial number 09/977,667 (a copy of this application was previously provided to the Examiner). The enclosed Notice of References Cited includes the references cited in the attached Information Disclosure Statement. Other references listed on the Notice have previously been disclosed to the Examiner of the instant application.

Once the disclosed references have been reviewed, it is requested that the Examiner place his initials next to the references on the list document and return a copy of


the initialed list document to the undersigned to indicate that the references have been considered.

Should the Examiner have any questions, he is invited to contact the undersigned at his convenience.

Respectfully submitted,

DORITY & MANNING, P.A.

By:

  
Christina L. Mangelsen, Patent Agent  
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Dated: 11/25/03



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DM-10/03

INFORMATION DISCLOSURE STATEMENT

In re Application of: Marshall, et al. Attorney Docket No: BAL-106 (17349)  
Serial No: 09/977,874 Date: November 25, 2003  
Filed: October 15, 2001 Art Unit: 1632  
Confirmation No: 3775 Our Customer ID: 22827  
Title: Composition For The Detection Of Our Account No: 04-1403  
Gastrointestinal Disorders

Commissioner for Patents  
U.S. Patent and Trademark Office  
Post Office Box 1450  
Alexandria, VA 22313-1450

Sir:

The following is an Information Disclosure Statement for the captioned patent application, pursuant to 37 CFR Sections 1.56, 1.97, and 1.98.

1.[x] Attached hereto is:

- a.[x] A list of materials for consideration per Rule 98(a)(1): 1 page(s)
- b.[x] A legible copy of each patent, publication, or other item listed per Rule 98(1)(2), unless not required per Rule 98(c) and/or (d) and as indicated on the attached list(s):  
5 item(s)
- c.[x] For each non-English language item listed, pursuant to Rule 98(a)(3), a concise explanation of the relevance thereof as it is presently understood by the individual designated in Rule 56(c) most knowledgeable about the content of such items: Relevance can be understood with reference to English abstract.  
[ ] Such explanation is provided in the Search Report from a corresponding application enclosed herewith along with any enclosed translation into English.

2.[x] This Information Disclosure Statement is being filed [CHECK ONE]:

a.[ ] WITHIN THREE MONTHS of the application filing date, national stage date of entry, or along with or after a request for continued examination, OR BEFORE the mailing date of a first Office Action on the merits, which ever event occurs last, WHEREFORE per Rule 97(b) NO filing fee or Rule 97(e) certificate is required.

b.[ ] AFTER the time periods of section 2.a above, but BEFORE a Final Action, Notice of Allowance OR an action that otherwise closes prosecution, WHEREFORE PER Rule 97(c) submitted herewith is [CHECK ONE]:

12/03/2003 HLE333 00000068 09977874

i.[ ] Certification per Rule 97(e); OR 01 FC:1806 180.00 OP

ii.[ ] Filing Fee per Rule 17(p) .....\$180.00

c.[x] AFTER a Final Action OR Notice of Allowance, but BEFORE payment of the issue fee, WHEREFORE per Rule 97(d) submitted herewith is:

i. Certification per Rule 97(e); AND

ii. Filing fee per Rule 17(p) .....\$180.00

3.[x] Rule 97(e) Certification; per Rule 97(e), the undersigned certifying party make the following certification statement [CHECK ONE]:

a.[ ] That each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement; OR

b.[x] That no item of information contained in this Information Disclosure Statement was cited in a foreign patent office in a counterpart foreign application and to the knowledge of the undersigned after making a reasonable inquiry, was known to any individual designated in Rule 56(c) more than three months prior to the filing of this statement.

CERTIFYING PARTY (if different from bottom signature; omission here indicates that certification is being made by signer per signature below).

Name: \_\_\_\_\_  
Address: \_\_\_\_\_

Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

- 4.[x] DEPOSIT ACCOUNT AUTHORIZATION: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This statement does not authorize charge of the issue fee in this case.

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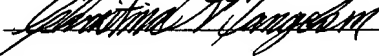
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DORITY & MANNING, P.A.

By: Christina L. Mangelsen, Patent Agent

Reg. No: 50,244

Signature: 

Date: November 25, 2003



|   |   |                             |
|---|---|-----------------------------|
| (R) 5/92)<br>Information Disclosure Statement List<br>By Applicant<br>Under 37 CFR Section 1.98(a) (1)<br>(Use several sheets if necessary) | Attorney Docket Number<br>BAL-106 (17349)                     | Serial Number<br>09/977,874 |
|   | Applicant<br>Marshall, et al.                                 |                             |
|   | Filing Date:<br>October 15, 2001<br>Confirmation No.:<br>3775 | Group<br>1654               |

- NOTE: If no indication is made in the column marked "COPY NOTE," the required legible copy of the corresponding item is submitted herewith; otherwise, a copy is not required and/or not submitted, for the following reason(s) [corresponding reason number is listed in "COPY NOTE" column]"
- (1) This item is cumulative, per Rule 98(c)
  - (2) A copy of this item was previously cited by or submitted to the U.S. Patent and Trademark Office in:  
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Relied on under 35 U.S.C. Section 120, per Rule 98(d)
  - (3) Both reasons (1) and (2) apply
  - (4) No legible complete copy is possessed, in custody of controlled, or readily available

| U.S. PATENT DOCUMENTS |                      |  |               |   |   |   |   |   |   |            |           |
|-----------------------|----------------------|--|---------------|---|---|---|---|---|---|------------|-----------|
| EXAMINER INITIALS     | PATENTEE NAME        |  | PATENT NUMBER |   |   |   |   |   |   | ISSUE DATE | COPY NOTE |
|                       | King                 |  | 5             | 4 | 9 | 8 | 5 | 2 | 8 | 03/12/1996 |           |
|                       | Heckenmuller, et al. |  | 5             | 6 | 7 | 9 | 5 | 7 | 0 | 10/21/1997 |           |

| FOREIGN PATENT DOCUMENTS |  |         |                 |   |   |   |   |   |   |                  |             |    |     |           |
|--------------------------|--|---------|-----------------|---|---|---|---|---|---|------------------|-------------|----|-----|-----------|
| EXAMINER INITIALS        |  | COUNTRY | DOCUMENT NUMBER |   |   |   |   |   |   | PUBLICATION DATE | TRANSLATION |    |     | COPY NOTE |
|                          |  |         |                 |   |   |   |   |   |   |                  | YES         | NO | N/A |           |
|                          |  | EP      | 0               | 3 | 6 | 9 | 2 | 9 | 2 | A1               | 05/23/1990  |    | X   |           |
|                          |  | FR      | 2               | 6 | 5 | 4 | 4 | 3 | 6 | A1               | 05/17/1991  |    | X   |           |
|                          |  |         |                 |   |   |   |   |   |   |                  |             |    |     |           |

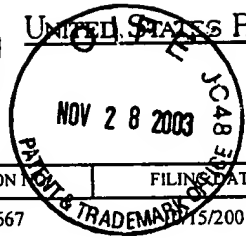
\*"NO" means that no copy of an English language translation is within the possession, custody, or control of, or is readily available to any individual designated in Rule 56(c).

| EXAMINER INITIALS | OTHER DOCUMENTS   | COPY NOTE |
|-------------------|---|-----------|
|                   | Specify author (if any), Title, Pertinent Pages, Date & Place of Publication<br>Article - <i>Development of a Chemiluminescent Urease Activity Assay for Helicobacter pylori Infection Diagnosis in Gastric Mucosa Biopsies</i> , Aldo Roda, Francesco Piazza, Patrizia Pasini, Mario Baraldini, Laura Zamboni, Stefania Fossi, Franco Bazzoli, and Enrico Roda, <i>Analytical Biochemistry</i> , Vol. 264, 1998, pp. 47-52 |           |
| EXAMINER          | DATE CONSIDERED   |           |
| Examiner:         | initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.   |           |

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/977,667      | 09/15/2001  | Donald J. McMichael  | 17350               | 3464             |

23556 7590 09/08/2003

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EXAMINER

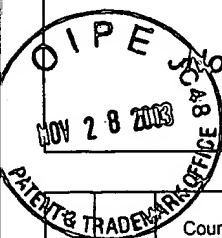
GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Notice of References Cited**

|                                       |  |  |             |
|---------------------------------------|--|--|-------------|
| Application/Control No.<br>09/977,667 |  | Applicant(s)/Patent Under<br>Reexamination<br>MCMICHAEL ET AL. |             |
| Examiner<br>Ralph Gitomer             |  | Art Unit<br>1651   | Page 1 of 1 |

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|   | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Name                | Classification |
|---|--|-----------------|---------------------|----------------|
| A | US-5,314,804 ✓                                   | 05-1994         | Boguslaski et al.   | 435/12         |
| B | US-5,420,016 ✓                                   | 05-1995         | Boguslaski et al.   | 435/12         |
| C | US-5,439,801 ✓                                   | 08-1995         | Jackson, Frank W.   | 435/12         |
| D | US-5,498,528                                     | 03-1996         | King, Wing          | 435/34         |
| E | US-5,593,851 ✓                                   | 01-1997         | Jackson, Frank W.   | 435/12         |
| F | US-5,668,011 ✓                                   | 09-1997         | Jackson, Frank W.   | 435/309.1      |
| G | US-5,679,570                                     | 10-1997         | Heckenmuller et al. | 435/287.9      |
| H | US-6,187,556 ✓                                   | 02-2001         | Lee et al.          | 435/34         |
| I | US-  |                 |                     |                |
| J | US-  |                 |                     |                |
| K | US-  |                 |                     |                |
| L | US-  |                 |                     |                |
| M | US-  |                 |                     |                |

**FOREIGN PATENT DOCUMENTS**

| * | Document Number<br>Country Code-Number-Kind Code | Date<br>MM-YYYY | Country | Name         | Classification |
|---|--|-----------------|---------|--------------|----------------|
| N | EP 369292  | 05-1990         | EP      | Klein et al. |                |
| O | FR 2654436                                       | 05-1991         | France  | Orsonneau    |                |
| P |  |                 |         |              |                |
| Q |  |                 |         |              |                |
| R |  |                 |         |              |                |
| S |  |                 |         |              |                |
| T |  |                 |         |              |                |

**NON-PATENT DOCUMENTS**

| * | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)   |  |  |  |  |
|---|---|--|--|--|--|
| U | Roda, A. Development of a Chemiluminescent Urease Activity Assay for HP Infection Diagnosis in Gastric Mucosa Biopsies. Analytical Biochemistry 264, 47-52, 1998. |  |  |  |  |
| V |   |  |  |  |  |
| W |   |  |  |  |  |
| X |   |  |  |  |  |

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.